## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:

David A. Mark et a

ATTY DOCKET NO.:

P97,1036

SERIAL NO:

09/025,363

T 0 1 1000 OFROUP ART UNIT:

1801

SCI U Z N

FILED:

February 18, 199

EXAMINER:

Unknown

INVENTION:

"CALORICALLY DENSITIONAL COMPOSITION"

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#### INFORMATION DISCLOSURE STATEMENT TRANSMITTAL LETTER

Assistant Commissioner for Patents Washington, D.C. 20231

SIR:

Submitted herewith is an Information Disclosure Statement for consideration in the above-identified application. This Information Disclosure Statement is submitted:

[X] Within three months (1) of filing date of a national application; (2) of date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; or (3) before the mailing date of a first Office Action on the merits, whichever occurs last. (No fee is required.)

[ ] After the mailing date of a first Office Action but before (1) mailing of a final action under 37 C.F.R. §1.113; or (2) mailing of a notice of allowance under §1.311, whichever occurs first.

[ ] Payment of the fee set forth in 37 C.F.R. §1.17(p) accompanies this submission; or

[ ] The certification specified in 37 C.F.R. §1.97(e) is made below. (No fee is required.)

After the mailing of (1) a final action under 37 C.F.R. §1.113; or (2) notice of allowance under 37 C.F.R. §1.311 whichever occurs first, but before payment of the issue fee. The certification specified in 37 C.F.R. §1.97(e) is made below. The Commissioner hereby is petitioned to consider the Information Disclosure Statement accompanying this submission. Payment for the Petition fee set forth in 37 C.F.R. §1.17(i)(1) accompanies this submission.

[ ] The undersigned counsel for applicant(s) hereby certifies each item of information identified in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

[ ] The undersigned counsel for applicant(s) hereby certifies that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, or to the knowledge of the undersigned, after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of the statement.

[ ] A check in the amount of \$\_\_\_\_\_ to cover any required fee is enclosed.

[X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 08-2290. A duplicate copy of this sheet is enclosed for this purpose.

Very respectfully,

HILL & SIMPSON

1 Profeszional Corporation

When phoning re this application, please call (312) 876-0200.

(Reg. No. 30,142) Hill & Simpson, P.C.

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Chicago, Illinois 60606 Telephone: (312) 876-0200

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C 20231 September 29, 1998.

ROBERT M. BARRETT



## INFORMATION DISCLOSURE STATEMENT

APPLICANT:

David A. Mark et al.

ATTY DOCKET NO.:

P97,1036

**SERIAL NO:** 

09/025,363

**GROUP ART UNIT:** 

1801

FILED:

February 18, 1998

**EXAMINER:** 

Unknown

**INVENTION:** 

"CALORICALLY DENSE NUTRITIONAL COMPOSITION"

**Assistant Commissioner for Patents** 

Washington, D.C. 20231

SIR:

In accordance with the provisions of 37 C.F.R. § 1.56, Applicants request that citation and examination of the references identified on the attached PTO-1449 form, copies of which are enclosed herewith in accordance with 37 C.F.R. 1.98, be made during the course of examination of the above-mentioned application for United States Patent.

## **U.S. PATENTS**

Patent Number	Inventor	<u>Date</u>
4,358,465	Brule et al.	11/09/82
4,361,587	Brule et al.	11/30/82
4,427,658	Maubois et al.	01/24/84
4,495,176	Brule et al.	01/22/85
4,670,268	Mahmoud	06/02/87
4,740,462	Brule et al.	04/26/88
4,753,963	Jandacek et al.	06/28/88
4,816,398	Brule et al.	03/28/89

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Patent Number	Inventor	<u>Date</u>
4,920,098	Cotter et al.	04/24/90
4,931,300	Monte	06/05/90
4,980,450	Brule et al.	12/25/90
5,028,589	Brule et al.	07/02/91
5,053,387	Alexander	10/01/91
5,055,446	Alexander et al.	10/08/91
5,156,875	Monte	10/20/92
5,166,189	Trimbo et al.	11/24/92
5,221,668	Henningfield et al.	06/22/93
5,223,285	DeMichele et al.	06/29/93
5,260,279	Greenberg	11/09/93
5,422,127	Dube et al.	06/06/95
5,438,042	Schmidl et al.	08/01/95
5,661,123	Stalker et al.	08/26/97
5,714,472	Gray et al.	02/03/98
5,723,446	Gray et al.	03/03/98

# **FOREIGN PATENTS**

Document Number	Country	<u>Date</u>
0 189 160	Europe	07/30/86

#### **OTHER DOCUMENTS**

Clintec Nutrition Company, Proper Nutrition For ICU Patients Is Critical, Brochure, 1994.

Clintec Nutrition Company, When You Create Such A Unique Enteral Formula, It's Hard Not To Create Attention, Brochure, 1994.

Clintec Nutrition Company, Crucial Needs Require A Curcial™ Solution, Brochure, 1994.

Clintec Nutrition Company, Crucial™ Compared To Perative®, Brochure, 1995.

Clintec Nutrition Company, When Your First Choice Has To Be Your Best Choice, Reabilan® Brochure (Undated).

Clintec Nutrition Company, Reabilan HN, Brochure (Undated).

Ross Laboratories Brochure, Specialized Elemental Nutrition With Glutamine - The Role of ALITRAQ<sup>TM</sup> Specialized Elemental Nutrition With Glutamine, 1991.

Ross Laboratories Brochure, Introducing ALITRAQ™ Specialized Elemental Nutrition
With Gluamine, 1992.

Ross Laboratories Brochure, *Introducing PERATIVE*<sup>TM</sup>, 1992.

Sandoz Nutrition Brochure, IMPACT®, 1993.

Sandoz Nutrition Brochure, INTRODUCING IMPACT®, 1989.

Sandoz Nutrition Brochure, IMPACT®, 1991.

Mead Johnson, Enteral Nutritionals Product Handbook, bearing Nos. A2688-2693.

Mead Johnson Enteral Nutritionals Brochure bearing Nos. B00083.

Mead Johnson Brochure bearing Nos. B00322-B00323.

Mead Johnson, Metabolic and Nutrition Support for Trauma and Burn Patients A Symposium, Abstracts, 1982, pp. 1-13.

Nutritional Care of Metabolically Stressed Patients, Proceedings from the Metabolic and Nutrition Support for Trauma and Burn Patients Symposium, White Sulphur Springs, West Virginia, 1983, pp. 1-77.

Principles of Nutritional Support: Proceedings From the Metabolic and Nutrition Support for Trauma and Burn Patients Symposium, White Sulphur Springs, West Virginia, 1982, pp. 1-25.

Symposium Highlights Metabolic and Nutrition Support for Trauma and Burn Patients, White Sulphur Springs, West Virginia, 1982, pp. 1-26.

TraumaCal, Feeding the Hypermetabolic Patient, Clinical Experience, A Symposium, 1983, pp. 1-74.

TraumaCal Product Cards bearing Nos. B000001-10.

TraumaCal Documents bearing Nos. B00088-105.

TraumaCal Document bearing No. B00181.

TraumaCal Document bearing Nos. B00261-265.

TraumaCal Document bearing No. B00293.

TraumaCal Document bearing Nos. B00384-385.

TraumaCal Label bearing No. B00441.

TraumaCal Brochure bearing Nos. B00567-570.

National Research Council, "Recommended Dietary Allowances, 10th Edition," Washington, D.C.: National Academy Press 1989.

Joint FAO/WHO Ad Hoc Expert Committee, "Protein and Energy Requirements: a joint FAO/WHO Memorandum," *Bulletin of the World Health Organization*, Vol. 57, 1979, pp. 65-79.

Bell et al., "Alternative lipid sources for enteral and parenteral nutrition: Long- and medium-chain triglycerides, structured triglycerides, and fish oils", *Journal of the American Dietetic Association*, Vol. 91, No. 1, 1991, pp. 74-78.

Bjerve et al., "Alpha-linolenic acid deficiency in man: effect of ethyl linolenate on plasma and erythrocyte fatty acid composition and biosynthesis of prostanoids", *Am J Clin Nutr*, Vol. 46, 1987, pp. 570-576.

Borum, "Role of Carnitine in Lipid Metabolism", *Lipids in Modern Nutrition*, New York: Raven Press, 1987, pp. 51-58.

Borum et al., "Carnitine content of liquid formulas and special diets", *Am J Clin Nutr*, Vol. 32, 1979, pp. 2272-2276.

Chernoff et al., "The effect of a very high-protein liquid formula (Replete®) on decubitus ulcer healing in long-term tube-fed institutionalized patients", *J Am Diet Assoc.*, Vol. 90, 1991.

Geggel et al., "Nutritional Requirement for Taurine in Patients Receiving Long-Term Parenteral Nutrition", *The New England Journal of Medicine*, Vol. 312, No. 3, 1985, pp. 142-146.

Greenberger et al., "Medium-Chain Triglycerides: Physiologic Considerations and Clinical Implications", *The New England Journal of Medicine*, Vol. 280, No. 19, 1969, pp. 1045-1058.

Hayes, "Vitamin-Like Molecules (D) Taurine", *Modern Nutrition in Health and Disease,*7th Edition, Philadelphia: Lea and Febiger, 1988, pp. 464-470.

Heymsfield et al., "Respiratory, cardiovascular, and metabolic effects of enteral hyperalimentation: influence of formula dose and composition", *The American Journal of Clinical Nutrition*, Vol. 40, 1984, pp. 116-130.

Holman, "Function and Biologic Activities of Essential Fatty Acids in Man", Fat Emulsion in Parenteral Nutrition, Chicago: American Medical Association, 1976, pp. 5-14.

Holt, "Medium Chain Triglycerides: A Useful Adjunct in Nutritional Therapy", Gastroenterology, Vol. 53, No. 6, 1967, pp. 961-966.

Kaunitz, "Clinical uses of medium-chain triglycerides", *Drug Therapy*, Vol. 8, 1978, pp. 91-96.

Law et al., "The Effect of Dietary Protein Depletion on Immunocompetence: The Importance of Nutritional Repletion Prior to Immunologic Induction", *Ann. Surg.*, Vol. 179, No. 2, 1974, pp. 168-173.

Mahan et al., "The Assessment of Nutritional Status", Krause's Food and Nutrition & Diet Therapy, 8th Edition, Philadelphia: W.B. Saunders Company, 1992, pp. 293-313.

Mascioli et al., "Intravenous Infusion of a Physical Mixture of Medium and Long Chain Triglyceride Emulsion", *Clin. Res.*, Vol. 33, 1985, 275A.

Nichols et al., "Magnesium supplementation in protein-calorie malnutrition", *The American Journal of Clinical Nutrition*, Vol. 31, 1978, pp. 176-188.

Randall et al., "Randomized Clinical Trial in Hospitalized Patients Using Intravenous Medium Chain Triglyceride Emulsions", *Clin. Res.*, Vol. 33, 1985, 276A.

Sailer et al., "Medium Chain Triglycerides in Parenteral Nutrition" *Journal of Parenteral* and Enteral Nutrition, Vol. 5, No. 2, 1981, pp. 115-119.

Simopoulos, "Omega-3 fatty acids in health and disease and in growth and development", *Am J Clin Nutr*, Vol. 54, 1991, pp. 438-63.

Sturman et al., "The Biology of Taurine in Nutrition and Development", *Adv. Nutr Res*, Vol. 3, 1980, pp. 231-299.

Sucher, "Medium Chain Triglycerides: A Review of Their Enteral Use in Clinical Nutrition", Nutrition in Clinical Practice, 1986, pp. 146-150.

Twyman et al., "High Protein Enteral Feedings: A Means of Achieving Positive Nitrogen Balance in Head Injured Patients", *Journal of Parenteral and Enteral Nutrition*, Vol. 9, No. 6, 1985, pp. 679-684.

Applicants look forward to early and favorable consideration of this matter.

Respectfully submitted,

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#### **CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited in the United States Postal Service, First Class Mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on September 29, 1998.